

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

- 1-8. (Canceled)
9. (Currently Amended) A method for ~~the treatment of a patient suffering from~~ reducing the frequency and/or intensity of chronic obstructive pulmonary disease (COPD) exacerbations experienced by a patient suffering from COPD, which method comprises administering to the patient via inhalation, ~~simultaneously, sequentially or separately, a therapeutically effective amount of~~ (i) a dose of a first active ingredient which is formoterol, a pharmaceutically acceptable salt or solvate thereof, or a solvate of such a salt; and (ii) a dose of a second active ingredient which is budesonide, wherein the method is effective to reduce the frequency and/or intensity of exacerbations in the patient, the first and second active ingredients are administered simultaneously, and the molar ratio of (a) formoterol in the first active ingredient to (b) the second active ingredient is from 1:2500 1:555 to 12:1 2:1.
10. (Canceled)
11. (Previously Presented) A method according to claim 9, wherein the first and/or second active ingredient is used in admixture with one or more pharmaceutically acceptable additives, diluents and/or carriers.
12. (Previously Presented) A method according to claim 9, wherein the first active ingredient is formoterol fumarate dihydrate.

13. (Currently Amended) A method according to claim 9, wherein the molar ratio ~~of the first active ingredient to the second active ingredient~~ is from ~~1:555~~ 1:133 to ~~2:1~~ 1:6.
14. (Previously Presented) A method according to claim 13 wherein the molar ratio is from 1:70 to 1:4.
15. (Currently Amended) A method according to claim 9 ~~further comprising providing the doses to the patient in the form of a dry,~~ wherein the first and second active ingredients are provided in powder form.
16. (Previously Presented) A method according to claim 15 wherein the first and second active ingredients are formulated as powder particles having a mass median diameter of less than 10  $\mu\text{m}$ .
17. (Previously Presented) A method according to claim 9 wherein the first and second active ingredients are provided in the form of an admixture.
- 18.-20. (Canceled)
21. (Currently Amended) A method according to claim 9 wherein the ~~amount of the dose of the first active ingredient is~~ administered to the patient in one or more unit doses per day, the amount of formoterol delivered to the patient by each unit dose of the first active ingredient being from about 2 to 120 nmol.
22. (Currently Amended) A method according to claim 21 wherein the amount of formoterol delivered to the patient by each unit ~~the dose of the first active ingredient~~ is from about 7 to 70 nmol.

23. (Currently Amended) A method according to claim 9 wherein the ~~amount of the dose of~~ the second active ingredient is administered to the patient in one or more unit doses per day, the amount of budesonide delivered to the patient by each unit dose being from about 0.1 to 5  $\mu\text{mol}$ .
24. (Currently Amended) A method according to claim 23 wherein the amount of budesonide delivered to the patient by each unit dose ~~the dose of the second active ingredient~~ is from about 0.15 to 4  $\mu\text{mol}$ .
25. (Currently Amended) A method according to claim 12 wherein the ~~amount of the dose of~~ formoterol fumarate dihydrate is administered to the patient in one or more unit doses per day, the amount of formoterol fumarate dihydrate delivered to the patient by each unit dose being from about 1 to 50  $\mu\text{g}$ .
26. (New) The method of claim 9, further comprising monitoring the number of exacerbations experienced by the patient over a period of 12 months of treatment.
27. (New) The method of claim 9, wherein the first active ingredient is administered in the form of one or more unit doses of formoterol fumarate dihydrate, each unit dose delivering 4.5  $\mu\text{g}$  of formoterol fumarate dihydrate to the patient; and the second active ingredient is administered in the form of one or more unit doses of budesonide, each unit dose of budesonide delivering 160  $\mu\text{g}$  of budesonide to the patient.
28. (New) The method of claim 27, wherein the unit doses of both the formoterol fumarate dihydrate and the budesonide are administered one to four times per day.

29. (New) The method of claim 9, wherein the first and second active ingredients are administered together from a pressurized metered dose inhaler (pMDI).
30. (New) The method of claim 9, wherein at least one of the first and second active ingredients is formulated in a propellant comprising one or both of P227 (heptafluoropropane) and P134(a) (tetrafluoroethane).
31. (New) The method of claim 12, wherein the first and second active ingredients are provided in admixture.
32. (New) The method of claim 31, wherein the first and second active ingredients are in powder form.
33. (New) The method of claim 32, wherein the first and second active ingredients are administered in admixture in the form of unit doses, each unit dose delivering to the patient 4.5 µg formoterol fumarate dihydrate and 160 µg budesonide.
34. (New) The method of claim 33, wherein the patient is administered one to four of the unit doses per day.
35. (New) The method of claim 32, wherein the first and second active ingredients are administered in admixture in the form of unit doses, each unit dose delivering to the patient 9 µg formoterol fumarate dihydrate and 320 µg budesonide.
36. (New) The method of claim 35, wherein the patient is administered one or two of the unit doses per day.

37. (New) The method of claim 9, wherein the first active ingredient is in the form of one or more unit doses of formoterol fumarate dihydrate, each unit dose delivering 4.5  $\mu\text{g}$  of formoterol fumarate dihydrate to the patient; and the second active ingredient, which may be separate from or in admixture with the first active ingredient, is administered in the form of one or more unit doses of budesonide, each unit dose of budesonide delivering 80  $\mu\text{g}$  of budesonide to the patient.
38. (New) The method of claim 37, wherein the unit doses of both the first active ingredient and the second active ingredient are administered one to four times per day.
39. (New) The method of claim 9, wherein the first active ingredient is administered in the form of one or more unit doses of formoterol fumarate dihydrate, each unit dose delivering 9  $\mu\text{g}$  of formoterol fumarate dihydrate to the patient; and the second active ingredient, which may be separate from or in admixture with the first active ingredient, is administered in the form of one or more unit doses of budesonide, each unit dose of budesonide delivering 160  $\mu\text{g}$  of budesonide to the patient.
40. (New) The method of claim 39, wherein the unit doses of both the first active ingredient and the second active ingredient are administered once or twice per day.
41. (New) A method for the treatment of a patient suffering from COPD, which method comprises administering to the patient via inhalation (i) a daily dose of a first active ingredient that is formoterol, a pharmaceutically acceptable salt or solvate thereof, or a solvate of such a salt, the daily dose of the first active ingredient delivering 2 to 120 nmol of formoterol to the patient; and (ii) a daily dose of a second active ingredient that is budesonide, the daily dose of the second active ingredient delivering 45 to 2200  $\mu\text{g}$  of budesonide to the patient, wherein the first active ingredient, which may be separate from or in admixture with the second active ingredient, is administered simultaneously with the

second active ingredient, and wherein the daily dose of each active ingredient is administered in one to four divided doses per day.

42. (New) The method of claim 41, wherein each daily dose of the first active ingredient is administered as one or more unit doses of formoterol fumarate dihydrate, each unit dose delivering 9 µg of formoterol fumarate dihydrate to the patient; and each daily dose of the second active ingredient, which may be separate from or in admixture with the first active ingredient, is administered as one or more unit doses of budesonide, each unit dose of budesonide delivering 320 µg of budesonide to the patient.
43. (New) The method of claim 42, wherein the unit doses of both the formoterol fumarate dihydrate and the budesonide are administered once or twice per day.
44. (New) The method of claim 41, wherein each daily dose of the first active ingredient is administered as one or more unit doses of formoterol fumarate dihydrate, each unit dose delivering 4.5 µg formoterol fumarate dihydrate to the patient; and each daily dose of the second active ingredient, which may be separate from or in admixture with the first active ingredient, is administered as one or more unit doses of budesonide, each unit dose delivering 80 µg of budesonide to the patient.
45. (New) The method of claim 41, wherein each daily dose of the first active ingredient is administered as one or more unit doses of formoterol fumarate dihydrate, each unit dose delivering 9 µg formoterol fumarate dihydrate to the patient; and each daily dose of the second active ingredient, which may be separate from or in admixture with the first active ingredient, is administered as one or more unit doses of budesonide, each unit dose delivering 160 µg of budesonide to the patient.

46. (New) The method of claim 45, wherein the unit doses of both the first active ingredient and the second active ingredient are administered once or twice per day.
47. (New) The method of claim 41, wherein each daily dose of the first active ingredient is administered as one or more unit doses of formoterol fumarate dihydrate, each unit dose delivering 4.5 µg formoterol fumarate dihydrate to the patient; and each daily dose of the second active ingredient, which may be separate from or in admixture with the first active ingredient, is administered as one or more unit doses of budesonide, each unit dose delivering 160 µg of budesonide to the patient.
48. (New) The method of claim 41, wherein the first and second active ingredients are administered together from a single pMDI.
49. (New) The method of claim 41, wherein at least one of the first and second active ingredients is formulated in a propellant comprising one or both of P227 and P134(a).
50. (New) The method of claim 41, wherein the method produces a reduction in frequency or intensity of COPD exacerbations in the patient.
51. (New) The method of claim 41, wherein the method produces an improvement in FEV<sub>1</sub> in the patient.
52. (New) A method for treating a patient suffering from COPD, which method comprises administering to the patient, via inhalation from a pMDI, a composition comprising (i) a first active ingredient that is formoterol, a pharmaceutically acceptable salt or solvate thereof, or a solvate of such a salt; (ii) a second active ingredient that is budesonide; and (iii) propellant P227, wherein the molar ratio of (a) formoterol in the first active ingredient to (b) the second active ingredient is from 1:70 to 1:4.

53. (New) The method of claim 52, wherein the patient inhales 4.5 or 9.0  $\mu\text{g}$  formoterol fumarate dihydrate once or twice per day and 80 or 160  $\mu\text{g}$  budesonide once or twice per day.
54. (New) The method of claim 52, wherein the method produces a reduction in frequency or intensity of COPD exacerbations in the patient.
55. (New) The method of claim 52, wherein the method produces an improvement in  $\text{FEV}_1$  in the patient.
56. (New) A method for the treatment of a patient suffering from COPD, which method comprises administering formoterol fumarate dihydrate and budesonide to the patient via inhalation, wherein the formoterol fumarate dihydrate and budesonide are administered simultaneously and optionally in admixture; the amount of formoterol fumarate dihydrate inhaled by the patient is 18  $\mu\text{g}$  per day; and the amount of budesonide inhaled by the patient is 640  $\mu\text{g}$  per day.
57. (New) A method for the treatment of a patient suffering from COPD, which method comprises administering to the patient via inhalation (i) a daily dose of a first active ingredient that is formoterol, a pharmaceutically acceptable salt or solvate thereof, or a solvate of such a salt, the daily dose of the first active ingredient delivering 42 nmol of formoterol to the patient per day; and (ii) a daily dose of a second active ingredient that is budesonide, the daily dose of the second active ingredient delivering 640  $\mu\text{g}$  of budesonide to the patient per day, wherein the first active ingredient is optionally in admixture with the second active ingredient, and the two active ingredients are administered simultaneously.



58. (New) A method for the treatment of a patient suffering from COPD, which method comprises administering formoterol fumarate dihydrate and budesonide to the patient via inhalation, wherein the formoterol fumarate dihydrate and budesonide are administered simultaneously, and optionally in admixture, in one to four unit doses per day; the amount of formoterol fumarate dihydrate delivered to the patient by each unit dose of formoterol fumarate dihydrate is 4.5  $\mu\text{g}$ ; and the amount of budesonide delivered to the patient by each unit dose of budesonide is 160  $\mu\text{g}$ .